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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/801,089	03/08/2001	David R. Phillips	MPI95-0151RCPA1DVIM	7657

7590 01/26/2005

INTELLECTUAL PROPERTY GROUP  
MILLENNIUM PHARMACEUTICALS, INC  
75 SIDNEY STREET  
CAMBRIDGE, MA 02139

EXAMINER

EWOLDT, GERALD R

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 01/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/801,089

Applicant(s)

PHILLIPS ET AL.

Examiner

G. R. Ewoldt, Ph.D.

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 23 November 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 21-23,30 and 32-44 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 21-23,30 and 32-44 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

**DETAILED ACTION**

1. A request for continued examination (RCE) under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed 11/23/04 in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's amendment and remarks, filed 11/23/04, have been entered.
2. Claims 21-23, 30, and 32-44 are pending and being acted upon.
3. Applicant has indicated a preference to amend the claims to recite the original claim language regarding signaling, i.e., a method of identifying integrin mediated signaling instead of the currently recited method of identifying outside-in or inside-out integrin mediated signaling. Applicant has argued that at the time of the invention signaling by integrins would have been recognized in the art as outside-in or inside-out signaling. Upon reconsideration, Applicant's amendment to this end would not be considered to be indefinite.
4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
5. Claims 22-23, 30, and 32-34 stand rejected under 35 U.S.C. § 112, first paragraph, as the specification does not contain a written description of the claimed invention, in that the disclosure does not reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed invention at the time the application was filed, for the reasons set forth in the action mailed 3/29/04 and maintained in the action mailed 8/31/04. This is a new matter rejection.

The specification and the claims as originally filed do not provide support for the invention as now claimed, specifically, the generic method comprising the steps of Claim 22 and the limitations of Claims 23 and 30-34.

6. Claims 21-23, 30, and 32-40 stand rejected under 35 U.S.C. § 112, first paragraph, as the specification does not contain a written description of the claimed invention, in that the disclosure does not reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed invention at the time the application was filed, for the reasons set forth in the action mailed 8/31/04. This is a new matter rejection.

The specification and the claims as originally filed do not provide support for the invention as now claimed, specifically, "a method to identify outside-in or inside-out signaling ... comprising the step of determining whether the cytoplasmic domain of said integrin is phosphorylated wherein a phosphorylated cytoplasmic domain indicates integrin-mediated outside-in or inside-out signaling".

7. The following are new grounds for rejection necessitated by Applicant's amendment.

8. Claims 21-23, 30, and 32-44 are rejected under 35 U.S.C. § 112, first paragraph, as the specification does not contain a written description of the claimed invention, in that the disclosure does not reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed invention at the time the application was filed. This is a new matter rejection.

The specification and the claims as originally filed do not provide support for the invention as now claimed, specifically,

A) A method wherein the  $\beta$  subunit does not contain an ITAM motif (Claim 21).

B) A method wherein the  $\beta$  subunit is phosphorylated (Claim 21).

C) The generic methods of Claims 43 and 44.

Regarding A), Applicant indicates that support for this new limitation can be found at page 19. A review of page 19 shows that the specification discloses a method of identifying integrin cytoplasmic signaling partners and not the method under examination. Also, the cite discloses only an ITAM motif lacking an isoleucine or leucine and not the generic ITAM motif of the claims. Limitations taught in a patentably distinct method, e.g., employing integrins lacking an ITAM motif, cannot be generically transferred to and recited in other methods such as the method of identifying integrin mediated signaling currently under examination.

Regarding B), a review of the specification and claims shows that original Claim 21 does not recite a method of identifying an integrin  $\beta$  subunit (the claim recites the identifying of the cytoplasmic domain of an integrin) and page 37 of the specification discloses only the identifying of phosphorylated tyrosine residues. Accordingly, the method as now claimed, i.e., a method of identifying a phosphorylated  $\beta$  subunit comprises the introduction of new matter into the claim.

Regarding C), Applicant indicates that support for new Claims 43 and 44 can be found at page 43. A review of the specification shows that page 43 discloses a specific example of an assay performed on aggregated platelets. As set forth previously, a description of specific experiments provides insufficient support for more generic claims, in this instance, a method employing only aggregated platelets cannot support the claimed method which could employ any cell type.

Applicant is advised that the instant amendment has added a third layer of new matter to the claims, thus rendering claims to a method that recites various unsupported limitations added by various different amendments. Applicant is advised that the most expeditious approach to forwarding prosecution might be a review of all of the pending claims and a citing of specific support for each of the claimed limitations in the claimed context. For example, in Claim 21, a citing of specific support for a method of identifying integrin mediated signaling comprising determining whether the cytoplasmic domain of an integrin  $\beta$  subunit, that does not contain an ITAM motif, is phosphorylated. As a further example, specific support could then be cited for the method of Claim 34 wherein all of the limitations of Claims 21 and 22 are disclosed, and further support is cited for the method then employing a carcinoma cell.

Applicant is again advised that the citing of limitations disclosed only in specific examples, or in other patentably distinct inventions that are not under examination, is not considered to be sufficient support for generic claims.

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claim 21 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Hibbs et al. (1991, IDS).

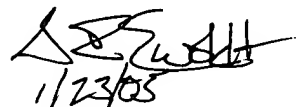
Hibbs et al. teaches a method to identify integrin mediated signaling (outside-in or inside-out) comprising determining whether the cytoplasmic domain of an integrin  $\beta$  subunit is phosphorylated (see particularly page 1228-1229, *Phosphoamino Acid Analysis*). Note that the  $\beta$  subunit under analysis comprises LFA-1/CD18/ $\beta$ 2 which lacks the ITAM motif (see page 19 of the specification).

The reference clearly anticipates the claimed invention.

11. No claim is allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (571) 272-0843. The examiner can normally be reached Monday through Thursday from 7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841.

13. **Please Note:** Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). Additionally, the Technology Center receptionist can be reached at (571) 272-1600.



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